Attachment L - 510(k) Summary K086680
Page 1 of 3

1. **Applicant Contact:**

Trudy Estridge
Director, Regulatory Affairs
Angiotech
Dulles Gateway Center
13921 Park Center Road, Suite 100
Herndon, VA 20171 USA
Phone: 703-796-8927
Fax: 703-673-0061
Email: testridge@angio.com

MAR 21 2008

Date Prepared: 03-07-08

2. **Name of Device:** Quill™ Self-Retaining System (SRS) comprised of PDO (Polydioxanone)
Common Name: Suture, Surgical, Absorbable, Polydioxanone
Classification Name: Absorbable polydioxanone surgical suture
Regulation 21 CFR 878.4840, Product Code NEW

3. **Identification of device(s) to which the submitted claims equivalence:**

The Quill™ Self-Retaining System (SRS) comprised of PDO is substantially equivalent to the following predicate device:

- Quill® Synthetic Absorbable Barbed Suture by Quill Medical Corporation, 510(k) K051609
- Quill™ Self-Retaining System (SRS) comprised of PDO (Polydioxanone) by Surgical Specialties Corporation dba Angiotech, 510(k) K071989

4. **Device Description:**

The Quill™ Self-Retaining System (SRS) comprised of PDO is a synthetic absorbable monofilament suture comprised of polyester [poly (p-dioxanone)] per 21 CFR 878.4840. It is available sterile, dyed violet (D&C Violet No. 2 per 21 CFR 74.3602) or undyed (beige) in various suture lengths and needle configurations in USP Sizes 3-0. Each suture has bi-directional barbs along the long axis of the suture monofilament.

The Quill™ Self-Retaining System (SRS) comprised of PDO approximates tissue by using the opposing barbs on the suture surface to imbed in the tissues after the surgeon precisely places the suture within the tissues. Each Quill™ Self-Retaining System (SRS) comprised of PDO pass provides the security of an interrupted suture strand without the added bulk of a knot. As with interrupted sutures, if the Quill™ Self-Retaining System (SRS) comprised of PDO breaks, the remaining suture passes will hold the wound edges in approximation.

K080680
Page 2 of 3

5. Intended Use of the Device:

Quill™ Self-Retaining System (SRS) comprised of PDO are indicated for soft tissue approximation where use of an absorbable suture is appropriate.

6. Characteristics of the device in comparison to those of the predicate device(s)

The Quill™ Self-Retaining System (SRS) comprised of PDO is equivalent to the predicate devices in its intended use of soft tissue approximation where use of an absorbable suture is appropriate and the technology of using barbs instead of knots to hold the tissue in approximation. The device modification is to decrease the spacing between the barbs on the suture length thereby increasing the number of barbs per linear length to increase tissue holding strength.

The comparison of the new device to the predicate devices is summarized below:

	Quill™ SRS comprised of PDO 510(k) ***TBD***	Quill® Synthetic Absorbable Barbed Suture 510(k) K051609	Quill™ SRS comprised of PDO, 510(k) K071989
Product Code	NEW	Identical	Identical
Suture Characteristic	Synthetic Absorbable Monofilament	Identical	Identical
Intended Use	Soft tissue approximation	Identical	Identical
Technique of Deployment	Attached needles	Identical	Identical
Technological Characteristic	Bi-directional barbs along the long axis of the suture monofilament	Identical	Identical
Material	Polydioxanone	Identical	Identical
Sterilization	EO	Identical	Identical
Packaging	Device wound onto inner support card, within a foil pouch within a poly/tyvek pouch	Identical	Identical

7. Safety and Performance:

The difference between the Quill™ Self-Retaining System (SRS) comprised of PDO and the above mentioned predicate devices does not raise any questions regarding the safety and effectiveness of the device. The device, as designed, is as safe and effective as its predicate devices.

8. Conclusion

Based on the design, material, function and intended use discussed herein, Angiotech believes the Quill™ Self-Retaining System (SRS) comprised of PDO is substantially equivalent to predicate devices currently marketed under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2008

Surgical Specialties Corporation
% Angiotech
Trudy D. Estridge, Ph.D.
13921 Park Center Road, Suite 100
Herndon, Virginia 21071

Re: K080680
Trade/Device Name: Quill™ Self-Retaining System (SRS) comprised of PDO
Regulation Code: 21 CFR 878.4840
Regulation Name: Absorbable polydioxanone surgical suture
Regulatory Class: II
Product Code: NEW
Dated: March 7, 2008
Received: March 10, 2008

Dear Dr. Estridge:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment F - Indications for Use Statement

510k number if known: K080680

Device Name: Quill™ Self-Retaining System (SRS) comprised of PDO

Indications for Use:

Quill™ Self-Retaining System (SRS) comprised of PDO is indicated for soft tissue approximation where use of an absorbable suture is appropriate.

Prescription Use ___√___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K080680